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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/718,729 | 11/24/2003 | Toru Matsumoto | Q78586 | 1837 |
| 23373 | 7590 | 10/26/2006 | EXAMINER | |
| SUGHRUE MION, PLLC 2100 PENNSYLVANIA AVENUE, N.W. SUITE 800 WASHINGTON, DC 20037 | | | NAFF, DAVID M | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1657 | |

DATE MAILED: 10/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/718,729

Applicant(s)

MATSUMOTO, TORU

Examiner

David M. Naff

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 July 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) 8-15, 24-27 and 29-34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 16-23 and 28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 11/24/03, 8/31/06.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Claims in the application are 1-34.

A response of 7/19/06 to a restriction requirement of 6/19/06 elected Group I claims 1-7, 16-23 and 28 with traverse.

5 The traverse requests that Group II claims 8-15 and 28 be examined with Group I claims 1-7, 16-23 and 28 since the enzyme electrode of claim 8 is an enzyme electrode with the elements of claim 1. While the enzyme electrode of claim 8 has the elements of claim 1, the elements of claim 8 are combined with elements not required by
10 claim 1, and the elements of claim 8 are not in the same relationship with respect to each other as in claim 1. For example, claim 1 requires a portion of an electrode on an insulating substrate, and an immobilized enzyme layer formed on a portion of the electrode, whereas claim 8 requires three layers between the electrode and the
15 immobilized enzyme layer, and the immobilized enzyme layer is formed on an ion-exchange resin film layer instead of the electrode. Therefore, the enzyme electrode of claim 1 can be produced and used without producing and using the enzyme electrode of claim 8, and the converse. Different searches and considerations for applying prior
20 art will be required for claim 8 not required for claim 1, and the converse. Finding claim 1 patentable does not necessarily mean that claim 8 is patentable since claim 1 might be considered patentable because the enzyme electrode operates without the additional layers and their relationship as required by claim 8. Furthermore, finding
25 claim 8 patentable does not necessarily mean that claim 1 is

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patentable since claim 8 might be considered patentable because of the additional layers and their relationship not required by claim 1. The different searches and considerations required with respect to inventions I and II will be a serious burden. The restriction requirement is still considered proper, and is adhered to and made final.

Claims 8-15, 24-27 and 29-34 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 7/19/06.

Claims examined on the merits are 1-7, 16-23 and 28.

Claim Objections

Claim 28 is objected to because of the following informalities: the claim depends on alternative claims that include claim 8 that is non-elected. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-7, 16-23 and 28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 1 and claims dependent thereon are unclear by claim 1 being unclear in lines 6-8 as to structure of a fluorine-containing polymer having a pendent group containing a fluoroalkylene block attached to an unfluorinated vinyl-based polymer. How "block" defines

5 "fluoroalkylene" is uncertain, and the structure of a pendant group that contains the fluoroalkylene block is uncertain. Furthermore, does the fluoroalkylene block provide the fluorine of the fluorine-containing polymer, or does the polymer contain fluorine in addition to the fluoroalkylene block? Claim 18 is indefinite for the same type

10 of reasons as set forth above in regard to claim 1.

In lines 2 and 3 of claim 1, "portion of electrode" is uncertain as to meaning and scope. The amount of electrode that is a portion is uncertain. Furthermore, if only a portion of an electrode is used, how is the portion obtained from the whole electrode, and what is done

15 with the part of the electrode remaining after obtaining the portion?

Dependent claims 3-6 are unclear as to the relationship of the fluoroalcohol ester of a polycarboxylic acid (A) and the alkylalcohol ester of a polycarboxylic acid (B) to the pendent group containing a fluoroalkylene block attached to an unfluorinated vinyl-based polymer

20 in claim 1. Where are (A) and (B) contained by the fluorine-containing polymer in relation to the fluoroalkylene block of the pendent group?

Claim 16 is unclear by not having clear antecedent basis for "the uppermost surface" (bridging lines 4 and 5). In line 6, the meaning

25 and scope of "essentially comprising" is unclear. How can essentially

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be comprising, and the converse. Line 10 is unclear as whether the grooves are on the surface of the polymer in line 7, or the film in line 6, or some other surface. In line 9, "many grooves" is uncertain as to the number that is many. It is suggested --- plurality --- be substituted. In line 10 "built" on the surface is unclear since it is unclear how "built" defines the grooves. This term should be deleted.

In claim 17, the meaning and scope is uncertain of the range "0.0001 or more and 1 or less" in line 4 of claim 17. The upper and lower limits encompass each other. Furthermore, how the range defines roughness is unclear since no units that can be measured are recited. If "fold" in line 4 is intended to be a unit for measuring roughness, it is unclear how this term defines roughness so one can measure roughness within the range claimed. The claim is further unclear as to where the roughness is located relative to the grooves of claim 16. In lines 3 and 4, claim 17 is unclear as to where the layer contains an "irregular shape". Additionally, is irregular shape in addition to the roughness required, or does the roughness provide the irregular shape?

Dependent claims 19-23 are unclear for the same type of reasons set forth above in regard to dependent claims 3-7.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the

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subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5

Claims 1-7 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Matsumoto (EP 0 969 282 A2) in view of McCaffrey et al (5,696,314) and Cozzette et al (5,200,051).

10

The claims are drawn to an enzyme electrode comprising an electrode on an insulating substrate, an immobilized enzyme layer on the electrode, an adhesion layer comprising a silane-containing compound over the immobilized enzyme layer, and a permeation-limiting layer comprising a fluorine-containing polymer having a pendent group containing a fluoroalkylene block attached to an unfluorinated vinyl-based polymer formed on the adhesion layer.

15

20

Matsumoto discloses an enzyme electrode that is the same as presently claimed except the enzyme electrode of Matsumoto contains a binding layer (adhesion layer) between an electrode and immobilized enzyme layer instead of between the immobilized enzyme layer and the permeation-limiting layer as claimed. For example, see Figures 1 and 2, and description of the figures (page 13, line 15 to page 14, line 40).

25

McCaffrey et al disclose a multilayer enzyme electrode (Figure 1) that contains an adhesive layer that promotes adhesion between an immobilized enzyme layer and an enzyme/polymer layer, and between a dielectric layer and a microporous layer (col 7, lines 47-59).

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Cozzette et al disclose a biosensor containing multiple layers. Adhesion between layers can be provided using a silane compound mixed with a solvent (col 26, section 5.1.2).

It would have been obvious provide an adhesion layer between the
5 immobilized enzyme layer and the permeation-limiting layer of
Matsumoto as suggested by McCaffrey et al using an adhesion layer to
promote adhesion between a dielectric layer and a microporous layer,
and between an immobilized enzyme layer and a enzyme/polymer layer,
and Cozzette et al disclosing providing adhesion between multiple
10 layers of a biosensor and using a reagent that provides adhesion
between the layers. Having good adhesion between the immobilized
enzyme layer and permeation-limiting layer of Matsumoto would have
been expected to be advantageous, and using an adhesion layer would
have been obvious in view of McCaffrey et al and Cozzette et al
15 providing adhesion between layers of a multiple layer enzyme electrode
and multiple layer biosensor by providing between layers a substance
that promotes adhesion. The conditions of dependent claims would have
been obvious from conditions disclosed by Matsumoto, and if needed
conditions disclosed by McCaffrey et al and Cozzette et al.

20 ***Claim Rejections - 35 USC § 103***

Claims 16, 18-23 and 28 are rejected under 35 U.S.C. 103(a) as
being unpatentable over Matsumoto in view of Schillig et al (6,461,861
B2).

The claims require an enzyme electrode formed on an insulating
25 substrate, an immobilized enzyme layer on the electrode, and a

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permeation-limiting layer formed over the immobilized enzyme layer, wherein the permeation-limiting layer consists of a film comprising a fluorine-containing polymer, and many grooves of a depth in the range of 0.1-100 nm built on the surface thereof.

5 Matsumoto discloses an enzyme electrode essentially the same as claimed except for disclosing the permeation-limiting layer containing grooves as claimed.

Schillig et al disclose a microbial membrane reactor for use in flow systems. The membrane may be fixed adjacent an electrode (col 1, line 47-48). Flow channels in the form of grooves (col 5, line 17) can be provided for flow of fluid over the surface of the membrane to provide substances metabolized by microorganisms contained by the membrane (col 2, lines 45-59 and col 3, lines 33-48).

15 It would have been obvious to provide the permeation-limiting layer of Matsumoto with grooves as suggested by Schillig et al to provide channels for flow of fluid to the immobilized enzyme layer. Selecting a preferred depth of the grooves would have been within the skill of the art and obvious. The conditions of dependent claims would have been obvious from conditions disclosed by Matsumoto.

20 ***Claim Rejections - 35 USC § 103***

Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claims 16, 18-23 and 28 above, and further in view of Cozzette et al.

The claim requires the permeation-limiting layer to have an irregular shape having a roughness.

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Matsumoto is described above.

Cozzette et al disclose a multilayer biosensor, and suggest that adhesion between layers can be provided by producing a rough topography between layers (col 26, lines 35-45).

5 When providing the permeation-limiting layer of the enzyme electrode of Matsumoto with grooves as suggested by Schillig et al as set forth above, it would have been obvious to provide the surface of the permeation-limiting layer next to the immobilized enzyme layer with roughness as suggested by Cozzette et al provide better adhesion
10 between the layers.

Double Patenting

15 The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference
20 claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*,
25 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

30 A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

35 Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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Claims 1-7 and 28 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-53 of U.S. Patent No. 6,280,587 B1 in view of McCaffrey et al and Cozzette et al.

5 It would be obvious to provide an adhesion layer between the immobilized enzyme layer and permeation-limiting layer of the enzyme electrode of the claims of the patent as suggested by McCaffrey et al and Cozzette et al for the type of reasons set forth above when applying these references to suggest an adhesion layer.

10 **Double Patenting**

Claims 16, 18-23 and 28 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-53 of U.S. Patent No. 6,280,587 B1 in view of Schillig et al.

15 It would have been obvious to provide the permeation-limiting layer of the enzyme electrode of the patent claims with grooves as suggested by Schillig et al for the type of reasons set forth above when applying Schillig et al to suggest grooves.

Double Patenting

20 Claims 17 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-53 of U.S. Patent No. 6,280,587 B1 in view of Schillig et al as set forth above, and further in view of Cozzette et al.

When providing the permeation-limiting layer of the enzyme
25 electrode of patent claims with grooves as suggested by Schillig et al

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as set forth above, it would have been obvious to provide the surface of the permeation-limiting layer next to the immobilized enzyme layer with roughness as suggested by Cozzette et al provide better adhesion between the layers.

Double Patenting

Claims 1-7 and 28 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-62 of U.S. Patent No. 6,464,848 B1 in view of Matsumoto (EP) and McCaffrey et al and Cozzette et al.

It would have been obvious to provide the biosensor of the patent claims with an immobilized enzyme layer on the electrode between the electrode and protection layer (permeation-limiting layer) as suggested by Matsumoto disclosing an immobilized enzyme layer between an electrode and permeation-limiting layer. It would have been further obvious to provide between the immobilized enzyme layer and permeation-limiting layer an adhesion layer as suggested by McCaffrey et al and Cozzette et al for reasons set forth above when applying these references to suggest an adhesion layer.

Double Patenting

Claims 16, 18-23 and 28 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-62 of U.S. Patent No. 6,464,848 B1 in view of Matsumoto and Schillig et al.

When providing the biosensor of the patent claims with an immobilized enzyme layer as suggested by Matsumoto as set forth above,

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it would have been further obvious to provide the protection layer (permeation-limiting layer) of the patent claims with grooves as suggested by Schillig et al for reasons set forth above when applying Schillig et al to suggest grooves.

5 **Double Patenting**

Claim 17 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-62 of U.S. Patent No. 6,464,848 B1 in view of Matsumoto and Schillig et al as set forth above, and further in view of Cozzette et al.

10 When providing the biosensor of the patent claims with an immobilized enzyme layer and grooves on the protection layer (permeation-limiting layer) as set forth above, it would have been obvious to provide roughness between the protection layer and the immobilized enzyme layer as suggested by Cozzette et al for the type
15 of reasons set forth when applying Cozzette et al to suggest roughness.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff
20 whose telephone number is 571-272-0920. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this
25 application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



David M. Naff
Primary Examiner
Art Unit 1651

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DMN
10/20/06